K040228

APR 2 9 2004

510(k) Summary

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as required by 807.92 (c)

for Medi-Stim VeriQ System, VQ1001 – VQ4122

Prepared January 28th, 2004

Submitted by: Medi-Stim AS
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Norway
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Contact Person: Jon H. Hoem, VP Sales & Marketing, Medi-Stim USA, Inc.

7601 Northland Drive, Mailstop A150, Brooklyn Park, MN55428

Tel. (763) 493 6664 direct / (612) 730 7310 cell

Fax (763) 391 9922

Device Trade Name: Medi-Stim VeriQ System

Common Name: Medical blood volume and velocity system with blood pressure and auxiliary data acquisition options.

Classification: Class II

Predicate Devices: **Medi-Stim AS**
Medi-Stim Butterfly Flowmeter (K992305)

Koven Technology, Inc.
Doppler Flowmeter DVM-4300T (K010452)
Doppler Flowmeter ES-1000SPM Smartdop (K903026)

12125 Woodcrest Executive Drive, Suite 220
St. Louis, MO 6314
Tel: 1 (800) 521 8342
Fax: (314) 542 6020

Description of Device
The Medi-Stim VeriQ System is used intraoperatively to measure blood volume and velocity waveforms in arteries and veins. Transit time and Doppler ultrasonography is used to obtain these measurements.

Intended Use of Device
The Medi-Stim VeriQ System is an intraoperative diagnostic system that utilizes ultrasonography to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device include, but are not restricted to, the following:

1. Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular-, transplantation- and neuro-surgery.

2. Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures.

3. Detection of normal and abnormal blood volume and Doppler velocity flow patterns during these procedures.

4. Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful accomplishment of surgery including detection and location of vessels during surgical procedures.

5. Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.

4.3. Indications for Use Statement

The Medi-Stim VeriQ System is an intraoperative diagnostic system that utilizes ultrasonography to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device are:

1. Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular-, transplantation- and neuro-surgery.

2. Simultaneous measurements of blood pressure, vascular resistance, interfaced physiological signals and other derived parameters during these procedures.

3. Detection of normal and abnormal blood volume and Doppler velocity flow patterns during these procedures.

4. Provides guidance to prepare surgical plans at the initiation of surgery and to support the successful accomplishment of surgery including detection and location of vessels during surgical procedures.

5. Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.

4.3.1. 510(k) Indications for Use Forms

Please find the Indications for Use Forms following.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 9 2004

Medi-Stim AS
c/o Mr. Jon H. Hoem
Vice President, Sale & Marketing
Medi-Stim USA, Inc.
7601 Northland Drive, Mailstop A150
Brooklyn Park, MN 55428

Re: K040228
Medi-Stim VeriQ System
Regulation Number: 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: 74 DPW
Dated: January 28, 2004
Received: February 2, 2004

Dear Mr. Hoem:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Medi-Stim VeriQ System, as described in your premarket notification:

PQ101011, PQ101012, PQ100021, PQ100031, PQ100041, PQ100051, PQ100022, PQ100032, PQ100042, PQ100052, PA100081, PA100101, PA100121, PA100161, PA100211, PA100271, PA100082, PA100101, PA100122, PA100161, PA100162, PR100251, PR100301, PR100351, PI100181, PI100141, PI100381, PI100121,

PC100181, PC103161, PC103161, PC103162, PC100141, PC100142, PC100382, PC100383, PC100122, PC100123, PC100124, PE100022, PE100032, PE100042, PE100052, PD110751, PD110752, PD120751, PD120752

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".
If you have any questions regarding the content of this letter, please contact Kachi Enyinna at (301) 443-8262.

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): K040228

Device Name: Medi-Stim VeriQ System

Indications For Use:

The Medi-Stim VeriQ System is an intraoperative diagnostic system that utilizes ultrasonography to guide surgeons to successfully plan and accomplish surgical interventions. The clinical indications for the device are:

1. Accurate transit time blood volume and Doppler velocity flow measurements during cardiovascular-, vascular-, transplantation- and neuro-surgery.

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5. Detection and quantification of the degree of stenosis in arteries by using the Doppler velocity profile.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Bodnar

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040228